Mr. Kenny McCleary
Eli Lilly and Company
P. O. Box 685
Lafayette, Indiana 47902

Re: Minor Source Modification No:
157-10818-00006

Dear Mr. McCleary:

Eli Lilly and Company applied for a Part 70 operating permit on October 10, 1996 for the pharmaceutical manufacturing plant. An application to modify the source was received on March 30, 1999. Pursuant to 326 IAC 2-7-10.5 the following emission units are approved for construction at the source:

A like-kind replacement of the old process tanks, identified as Gen'l Tank 28-13, with a capacity of 2,000 gallons, and Gen'l Tank 28-1A with a capacity of 300 gallons. The volatile organic compounds (VOC) emissions from these tanks will be controlled by the existing Regenerative Thermal Oxidizer (RTO) under Construction Permit CP157-1980) or the condensers.

The point source emissions from the process vessels may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device. Also, in the event that the RTO is unavailable, Lilly would continue manufacturing operations in the process vessels using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from these replacement tanks will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from these replacement tanks will be voluntarily controlled by scrubbers. The nitrogen oxides emissions from these replacement tanks will be voluntarily controlled by scrubbers.

The proposed Minor Source Modification approval will be incorporated into the pending Part 70 permit application pursuant to 326 IAC 2-7-10.5(l)(3). The source may begin operation upon issuance of the source modification approval.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. If you have any questions on this matter call (800) 451-6027, press 0 and ask for Aida De Guzman or extension (3-4972), or dial (317) 233-4972.

Sincerely,

Paul Dubenetzky, Chief
Permits Branch
Office of Air Management

Attachments
APD
cc: File - Tippecanoe County
U.S. EPA, Region V
Tippecanoe County Health Department
Air Compliance Section Inspector - Eric Courtright
Compliance Data Section
Administrative and Development - Janet Mobley
Technical Support and Modeling

PART 70 MINOR SOURCE MODIFICATION
OFFICE OF AIR MANAGEMENT

Eli Lilly and Company
1650 Lilly Road
Shadeland, Indiana 47905

(herein known as the Permittee) is hereby authorized to construct and operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this approval.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Minor Source Modification No.:157-10818-00006	
Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

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SECTION A SOURCE SUMMARY

This approval is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM). The information describing the emission units contained in conditions A.1 through A.2 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this approval pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a pharmaceutical manufacturing plant.

Responsible Official:	Kenny McCleary
Source Address:	1650 Lilly Road, Shadeland, Indiana 47905
Mailing Address:	P. O. Box 685, Lafayette, Indiana 47902
Phone Number:	765-477-4006
SIC Code:	2834 & 2879
County Location:	Tippecanoe
County Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Permit Program Existing Major, under PSD Rules; Major Source, Section 112 of the Clean Air Act

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This Pharmaceutical Manufacturing source is approved to construct and operate the following emission units and pollution control devices:

The installation of new process tanks, identified as Gen'l Tank 28-13, with a capacity of 2,000 gallons, and Gen'l Tank 28-1A, with a capacity of 300 gallons for a like-kind replacement of the old process tanks. The volatile organic compounds (VOC) emissions from these tanks will be controlled by the existing Regenerative Thermal Oxidizer (RTO) under Construction Permit CP157-1980 or the condensers.

The point source emissions from the process vessels may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device. Also, in the event that the RTO is unavailable, Lilly would continue manufacturing operations in the process vessels using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from these replacement tanks will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from these replacement tanks will be voluntarily controlled by scrubbers. The nitrogen oxides emissions from these replacement tanks will be voluntarily controlled by scrubbers.

A.3 Part 70 Permit Applicability [326 IAC 2-7-2]

This Pharmaceutical manufacturing source has submitted a Part 70 permit application TV157-6879-00006 on October 10, 1996, pursuant to 326 IAC 2-7-2 (Applicability) because:.

(a) It is a major source, as defined in 326 IAC 2-7-1(22);

(b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONSTRUCTION CONDITIONS

B.1 Permit No Defense [IC 13]

This approval to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

B.2 Definitions [326 IAC 2-7-1]

Terms in this approval shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, any applicable definitions found in IC 13-11, 326 IAC 1-2 and 326 IAC 2-7 shall prevail.

B.3 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this approval becomes effective upon its issuance.

SECTION C GENERAL OPERATION CONDITIONS

C.1 Certification [326 IAC 2-7-4(f)] [326 IAC 2-7-6(1)]

(a) Where specifically designated by this approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, and any other certification required under this approval, shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) One (1) certification shall be included, on the attached Certification Form, with each submittal.

(c) A responsible official is defined at 326 IAC 2-7-1(34).

C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

(a) If required by specific condition(s) in Section D of this approval, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMP) within ninety (90) days (this time frame is determined on a case by case basis but no more than ninety (90) days) after issuance of this approval, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions;

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If due to circumstances beyond its control, the PMP cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that lack of proper maintenance does not cause or contribute to a violation of any limitation on emissions or potential to emit.

(c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM.

C.3 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

(a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.

(b) Any application requesting an amendment or modification of this approval shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Management
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

C.4 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.5 Operation of Equipment [326 IAC 2-7-6(6)]

All air pollution control equipment listed in this approval and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

C.6 Stack Height [326 IAC 1-7]

The Permittee shall comply with the applicable provisions of 326 IAC 1-7 (Stack Height Provisions), for all exhaust stacks through which a potential (before controls) of twenty-five (25) tons per year or more of particulate matter or sulfur dioxide is emitted by using good engineering practices (GEP) pursuant to 326 IAC 1-7-3.

Testing Requirements [326 IAC 2-7-6(1)]

C.7 Performance Testing [326 IAC 3-6]

(a) All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this approval, utilizing methods approved by IDEM, OAM.

A test protocol, except as provided elsewhere in this approval, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The Permittee shall submit a notice of the actual test date to the above address so that it is received at least two weeks prior to the test date.

(b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the Commissioner, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

The documentation submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

C.8 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

Compliance with applicable requirements shall be documented as required by this approval. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment, no more than ninety (90) days (this time frame is determined on a case by case basis but no more than ninety (90) days) after receipt of this approval. If due to circumstances beyond its control, this schedule cannot be met, the Permittee may extend the compliance schedule an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

C.9 Maintenance of Monitoring Equipment [326 IAC 2-7-5(3)(A)(iii)]

(a) In the event that a breakdown of the monitoring equipment occurs, a record shall be made of the times and reasons of the breakdown and efforts made to correct the problem. To the extent practicable, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less frequent than required in Section D of this approval until such time as the monitoring equipment is back in operation. In the case of continuous monitoring, supplemental or intermittent monitoring of the parameter should be implemented at intervals no less than one (1) hour (this time frame is determined on a case by case basis until such time as the continuous monitor is back in operation.

(b) The Permittee shall install, calibrate, quality assure, maintain, and operate all necessary monitors and related equipment. In addition, prompt corrective action shall be initiated whenever indicated.

C.10 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this approval exceed the level specified in any condition of this approval, the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.

(b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility.

The documents submitted pursuant to this condition do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.11 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]

(a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment is operating at normal representative conditions.

(b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.

(c) If the equipment is operating but abnormal conditions prevail, additional observations and sampling should be taken with a record made of the nature of the abnormality.

(d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.

(e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.

(f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

C.12 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

(a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Records of required monitoring information shall include, where applicable:

(1) The date, place, and time of sampling or measurements;

(2) The dates analyses were performed;

(3) The company or entity performing the analyses;

(4) The analytic techniques or methods used;

(5) The results of such analyses; and

(6) The operating conditions existing at the time of sampling or measurement.

(c) Support information shall include, where applicable:

(1) Copies of all reports required by this approval;

(2) All original strip chart recordings for continuous monitoring instrumentation;

(3) All calibration and maintenance records;

(d) All record keeping requirements not already legally required shall be implemented within ninety (90) days of approval issuance.

C.13 General Reporting Requirements [326 IAC 2-7-5(3)(C)]

(a) The reports required by conditions in Section D of this approval shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Management
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(b) Unless otherwise specified in this approval, any notice, report, or other submission required by this approval shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAM, on or before the date it is due.

(c) Unless otherwise specified in this approval, any semi-annual report shall be submitted within thirty (30) days of the end of the reporting period. The report does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(d) The first report shall cover the period commencing on the date of issuance of this approval and ending on the last day of the reporting period.

SECTION D.1 FACILITY OPERATION CONDITIONS

The installation of new process tanks, identified as Gen'l Tank 28-13, with a capacity of 2,000 gallons, and Gen'l Tank 28-1A, with a capacity of 300 gallons for a like-kind replacement of the old process tanks. The volatile organic compounds (VOC) emissions from these tanks will be controlled by the existing Regenerative Thermal Oxidizer (RTO) under Construction Permit CP157-1980 or the condensers.

The point source emissions from the process vessels may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device. Also, in the event that the RTO is unavailable, Lilly would continue manufacturing operations in the process vessels using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from these replacement tanks will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from these replacement tanks will be voluntarily controlled by scrubbers. The nitrogen oxides emissions from these replacement tanks will be voluntarily controlled by scrubbers.

Emissions Limitation and Standards

D.1.1 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing (326 IAC 8-5-3)

(a) Pursuant to 326 IAC 8-5-3 the following outlet gas temperature when using condensers to control the VOC emissions from these process tanks including the existing facilities at the plant shall not exceed the following:

(1) minus twenty-five degrees Celsius (-25 ^{0}C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);

(2) minus fifteen degrees Celsius (-15 ^{0}C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);

(3) zero degrees Celsius (0 ^{0}C) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (one and five-tenths (1.5) pounds per square inch);

(4) ten degrees Celsius (10 ^{0}C) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (one (1) pounds per square inch); or

(5) twenty -five degrees Celsius (25 ^{0}C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pounds per square inch).

Compliance Determination Requirements

D.1.2 Testing Requirements [326 IAC 2-7-6(1),(6)][326 IAC 2-1.1-11]

The Permittee is not required to test the facilities by this permit. The testing required for these facilities will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3. However, IDEM may require compliance testing when necessary to determine if the facilities are in compliance. If testing is required by IDEM compliance with Condition D.1.1 shall be determined by a performance test conducted in accordance with Section C - Performance Testing.

D.1.3 Volatile Organic Compounds 326 IAC 8-5-3(b)(5)(6)

(a) Pursuant to 326 IAC 8-5-3(b)(5) the Permittee shall install covers on all in process tanks that contain VOC's. These covers shall be kept closed unless production sampling, maintenance, or inspection procedures require operator access.

(b) Pursuant to 326 IAC 8-5-3(b)(6) the Permittee shall repair all visible leaks containing VOC. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

D.1.4 Monitoring For VOC Emissions

(a) The VOC emissions from the proposed replacement process vessels Gen'l Tank 28-13 and Gen'l Tank 28-1A shall be in compliance with 326 IAC 8-5-3 provided that:

(1) the Regenerative Thermal Oxidizers (RTO) or Condensers (when Lilly elects to control the VOC by condensers) shall operate at all times the equipment being controlled are in operation;

(2) when the VOC emissions from the proposed process tanks including the existing facilities are controlled by the RTO, the RTO's operating temperature shall be maintained at 1600^0F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of the volatile organic compounds. The operating temperature of the RTO shall be recorded and monitored continuously;

(3) when the VOC emissions from the proposed process tanks including the existing facilities are controlled by the condensers, the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.1;

(4) the Permittee records the time during which the RTO or condensers, serving the proposed process tanks, including the existing facilities, were not operated;

(5) the Permittee records the reason the RTO or condensers were not operated;

(6) the Permittee records the corrective actions taken to bring the RTO or condensers to normal operation; and

(7) the Permittee records the number of hours the proposed process tanks, including the existing facilities were vented to points other than the RTO or a condenser complying with 326 IAC 8-5-3.

D.1.5 National Emission Standards for Hazardous Air Pollutants (NESHAPs) 40 CFR Part 63, Subparts I and H

That the owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive VOC emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

D.1.6 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)

The proposed replacement process tanks, Gen'l Tank 28-13; and Gen'l Tank 28-1A are subject to 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the year 2001.

D.1.7 Malfunction Condition

Pursuant to 326 IAC 1-6-2 (Records; Notice of Malfunction):

(a) A record of all malfunctions, including startups or shutdowns of any facility or emission control equipment, which result in violations of applicable air pollution control regulations or applicable emission limitations shall be kept and retained for a period of three (3) years and shall be made available to the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM) or appointed representative upon request.

(b) When a malfunction of any facility or emission control equipment occurs which lasts more than one (1) hour, said condition shall be reported to OAM. The Permittee is encouraged, but not required, to use the Malfunction Report Form (2 pages) attached to this permit. Notification shall be made by telephone or facsimile, as soon as practicable, but in no event later than four (4) daytime business hours after the beginning of said occurrence.

(c) Failure to report a malfunction of any emission control equipment subject to the requirements of 326 IAC 1-6 shall constitute a violation of 326 IAC 1-6 and any other applicable rules. Information of the scope and expected duration of the malfunction shall be provided, including the items specified in 326 IAC 1-6-2(a)(1) through (6).

(d) Malfunction is defined as any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

Record Keeping and Reporting Requirements

D.1.8 Record Keeping Requirements

(a) The Permittee shall maintain records in accordance with (1) through (3) as follows:

(1) The malfunction report of the RTOs; and other malfunction reports of the facilities when the RTO is operating but the facilities are not venting to the RTO;

(2) The RTO's operating temperature;

(3) The number of hours the proposed process tanks including existing facilities were vented to points other than the RTO or the condenser; and

(b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR MANAGEMENT
COMPLIANCE DATA SECTION

FAX NUMBER - 317 233-5967

This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

THIS FACILITY MEETS THE APPLICABILITY REQUIREMENTS BECAUSE: IT HAS POTENTIAL TO EMIT 25 LBS / HR PARTICULATES ?_____, 100 LBS / HR VOC ?_____, 100 LBS / HR SULFUR DIOXIDE ?_____ OR 2000 LBS / HR OF ANY OTHER POLLUTANT ?_____ EMISSIONS FROM MALFUNCTIONING CONTROL EQUIPMENT OR PROCESS EQUIPMENT CAUSED EMISSIONS IN EXCESS OF APPLICABLE LIMITATION _____.

THIS MALFUNCTION RESULTED IN A VIOLATION OF: 326 IAC _____ OR, PERMIT CONDITION # _____ AND / OR PERMIT LIMIT OF _____

THIS INCIDENT MEETS THE DEFINITION OF 'MALFUNCTION' AS LISTED ON REVERSE SIDE ? Y N

THIS MALFUNCTION IS OR WILL BE LONGER THAN THE ONE (1) HOUR REPORTING REQUIREMENT ? Y N

COMPANY: Eli Lilly and Company PHONE NO. (765) 477-4867

LOCATION: (CITY AND COUNTY) Shadeland, Indiana
PERMIT NO. 157-10818 AFS PLANT ID: 157-00006 AFS POINT ID: _____ INSP: _____
CONTROL / PROCESS DEVICE WHICH MALFUNCTIONED AND REASON: _____

DATE / TIME MALFUNCTION STARTED: _____/_____/ 19____ _____ AM / PM

ESTIMATED HOURS OF OPERATION WITH MALFUNCTION CONDITION:
_____

DATE / TIME CONTROL EQUIPMENT BACK-IN SERVICE_____/_____/ 19____ _____ AM / PM

TYPE OF POLLUTANTS EMITTED: TSP, PM-10, SO2, VOC, OTHER: _____

ESTIMATED AMOUNT OF POLLUTANT EMITTED DURING MALFUNCTION:

MEASURES TAKEN TO MINIMIZE EMISSIONS:

REASONS WHY FACILITY CANNOT BE SHUTDOWN DURING REPAIRS:

CONTINUED OPERATION REQUIRED TO PROVIDE ESSENTIAL* SERVICES:
_____
CONTINUED OPERATION NECESSARY TO PREVENT INJURY TO PERSONS:_____
CONTINUED OPERATION NECESSARY TO PREVENT SEVERE DAMAGE TO EQUIPMENT:_____
INTERIM CONTROL MEASURES: (IF APPLICABLE)

MALFUNCTION REPORTED BY: _____TITLE:_____
(SIGNATURE IF FAXED)
MALFUNCTION RECORDED BY: _____DATE:_____TIME:_____

FAX NUMBER - 317 233-5967 *SEE REVERSE

Please note - This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

326 IAC 1-6-1 Applicability of rule

Sec. 1. The requirements of this rule (326 IAC 1-6) shall apply to the owner or operator of any facility which has the potential to emit twenty-five (25) pounds per hour of particulates, one hundred (100) pounds per hour of volatile organic compounds or SO2, or two thousand (2,000) pounds per hour of any other pollutant; or to the owner or operator of any facility with emission control equipment which suffers a malfunction that causes emissions in excess of the applicable limitation.

326 IAC 1-2-39 "Malfunction" definition

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner. (Air Pollution Control Board; 326 IAC 1-2-39; filed Mar 10, 1988, 1:20 p.m. : 11 IR 2373)

***Essential services** are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

If this item is checked on the front, please explain rationale:

_____

_____

Indiana Department of Environmental Management
Office of Air Management

Technical Support Document (TSD) for a Minor Source Modification Permit

Source Background and Description

Source Name:	**Eli Lilly and Company, Tippecanoe Laboratories**
Source Location:	**1650 Lilly Road, Shadeland, Indiana 47902**
County:	**Tippecanoe**
SIC Code:	**2834 & 2879**
Operation Permit No.:	**TV157-6879-00006**
Operation Permit Issuance Date:	**Pending**
Minor Source Modification No.:	**157-10818-00006**
Permit Reviewer:	**Aida De Guzman**

The Office of Air Management (OAM) has reviewed a modification application from Eli Lilly and Company relating to the installation of new process tanks, identified as Gen'l Tank 28-13, with a capacity of 2,000 gallons, and Gen'l Tank 28-1A, with a capacity of 300 gallons for a like-kind replacement of the old process tanks. The volatile organic compounds (VOC) emissions from these tanks will be controlled by the existing Regenerative Thermal Oxidizer (RTO) under Construction Permit CP157-1980) or the condensers.

The point source emissions from the process vessels may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device. Also, in the event that the RTO is unavailable, Lilly would continue manufacturing operations in the process vessels using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from these replacement tanks will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from these replacement tanks will be voluntarily controlled by scrubbers. The nitrogen oxides emissions from these replacement tanks will be voluntarily controlled by scrubbers.

History

The source has submitted a Title V permit (TV 157-6879-00006) on October 10, 1996, and it is still pending for issuance.

Recommendation

The staff recommends to the Commissioner that the Minor Source Modification be approved. This recommendation is based on the following facts and conditions:

The above tanks will have a PTE regulated pollutants that exceeds the emission thresholds in 326 IAC 2-7-10.5(f) which subject a process to the significant source modification. However, since the tanks will replace or repair a part or piece of equipment in an existing process, these new process tanks Gen'l Tank 28-13 and Gen'l Tank 28-1A. qualifies for Minor Source Modification under 326 IAC 2-7-10.5(d)(8).

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on March 30 Additional information was received on April 27, 1999.

Emission Calculations

The new process tanks will have the same characteristics as the existing process tanks (see below table).

Proposed Process Tanks	Capacity (Gallons)	Existing Process Tanks	Capacity (gallons)	Control Devices
Gen'l Tank 28-13	2,000	Gen'l Tank 28-13	2,000	RTO, Scrubber
Gen'l Tank 28-1A	300	Gen'l Tank 28-1A	300	RTO, Scrubber

Below emissions are similar with the PTE of the replaced process tanks. No emission increase will result from this like-kind replacement. (see below summary of emissions).

PTE (tons/year)						
Proposed Process Tanks	Capacity (Gallons)	VOC	CO	SO2	NOx	HAPs
Gen'l Tank 28-13	2,000	3.9	39.55	60.6	<25	27.9
Gen'l Tank 28-1A	300	0.62	5.93	9.09	0.51	4.22
TOTAL		4.52	45.48	69.69	<25	32.12

The above emissions for VOC point sources from process vessels were determined using the equation found in the EPA Guideline for Control of VOC from Manufacture of Synthesized Pharmaceutical Products, EPA-450/2-78-029. The process vessel VOC emission estimates are based on a combination of the typical unit operations that are done to perform a process. The steps in the process includes charging, heating, tank evacuation with vacuum distillations, atmospheric distillations, centrifuging and drying.

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA."

Pollutant	Potential To Emit (tons/year)
PM	0.0
PM-10	0.0
SO_2	69.69
VOC	4.52
CO	45.48
NO_x	<25
HAPs Combined	32.12

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

Actual Emissions

No previous emission data has been received from the source.

Limited/Controlled Potential to Emit

The table below summarizes the total potential to emit, reflecting all limits from the modification:

	Limited/Controlled Potential to Emit (tons/year)						
Process/facility	**PM**	**PM-10**	**SO_2**	**VOC**	**CO**	**NO_X**	**HAPs**
Process Tanks Gen'l Tanks 28-13 & 28-1A	0.0	0.0	3.48	0.452	2.27	<25	5.9
Total Emissions	0.0	0.0	3.48	0.452	2.27	<25	5.9

VOC is controlled by the condenser, with a control efficiency of 90% or the condenser in series with the RTO, or just the RTO alone. The condenser is used in this calculation to determine the controlled VOC PTE.

VOC controlled PTE = 4.52 * (1-.90)
= 0.452

CO is voluntarily controlled by the RTO with a control efficiency of 95%

CO controlled PTE = 45.48 * (1-0.95)
= 2.27

SO2 is voluntarily controlled by the scrubbers with a control efficiency of 95%

SO2 controlled PTE = 69.69 * (1-0.95)
= 3.48

County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status (attainment, maintenance attainment, or unclassifiable; severe, moderate, or marginal nonattainment)
PM-10	attainment
SO_2	attainment
NO_2	attainment
Ozone	attainment
CO	attainment
Lead	attainment

(a) Volatile organic compounds (VOC) and oxides of nitrogen (NOx) are precursors for the formation of ozone. Therefore, VOC and NO_X emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone.

Federal Rule Applicability

(a) New Source Performance Standards (NSPS)
(1) 40 CFR Part 60, Subpart Kb - Standards of Performance for Volatile Organic Liquid Storage Vessels (including Petroleum Liquid Storage Vessels) for which construction, reconstruction, or modification commenced after July 23, 1994.

This NSPS is not applicable to the new tanks, because they are process tanks and not storage tanks.

(2) There are no other New Source Performance Standards (NSPS)(326 IAC 12 and 40 CFR Part 60) applicable to this source.

(b) National Emission Standards for Hazardous Air Pollutants (NESHAPs)

(1) 40 CFR Part 63, Subparts I and H - National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes Subject to the Negotiated Regulation for Equipment Leaks; and 40 CFR Part 63, Subpart H - National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks.

This NSPS applies to the proposed process vessels when Methylene Chloride is used in them, pursuant to Section (b)(5) of this NSPS (Pharmaceutical Production Processes) using Methylene Chloride or Carbon Tetrachloride).

Lilly will comply with these requirements with the implementation of Lilly's Leak Detection and Repair Program (LDAR) when Methylene Chloride is used in them.

(2) 40 CFR Part 63, Subpart B - Requirements for Control Technology Determinations for Major Sources in Accordance with the Clean Air Act Amendments of 1990, Sections 112(g)(2)(B).

The requirements of Part 63.40 through Part 63.44 of this Subpart apply to any owner, or operator who construct or reconstruct a major source of HAPs after the effective date of section 112(g)(2)(B) and the effective date of a Title V permit Program in the State or local jurisdiction in which the major source in question has been specifically or exempted from regulation under a standard issued pursuant to sections 112(d), 112(h) or 112(j) and incorporated in another subpart of part 63.

This NSPS is not applicable to these process tanks for the following reasons:

(a) This project does not constitute construction, reconstruction of a process or production unit because (1) the fabrication, erection or installation covered by this application does not constitute a collection of all the equipment necessary to the production of an intermediate or final product; and (2) the fixed capital cost of this project does not exceed 50% of the fixed capital cost for the replacement of any of the affected process or production unit.

(b) The proposed replacement process tanks, Gen'l Tank 28-13; and Gen'l Tank 28-1A are regulated under 40 CFR Part 63, Subpart GGG - National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production, which was promulgated on September 21, 1998.

These process tanks shall be in compliance with this NESHAP by the year 2001.

State Rule Applicability - Entire Source

(a) 326 IAC 2-6 (Emission Reporting)

This source is subject to 326 IAC 2-6 (Emission Reporting), because it is a Title V source, which has the potential to emit more than one hundred (100) tons per year) of at least one of the criteria pollutants. Pursuant to this rule, the owner/operator of the source must annually submit an emission statement for the source. The annual statement must be received by July 1 of each year and contain the minimum requirement as specified in 326 IAC 2-6-4.

The submittal should cover the period defined in 326 IAC 2-6-2(8)(Emission Statement Operating Year).

(b) 326 IAC 5-1 (Visible Emissions Limitations)
Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this permit:

(c) Opacity shall not exceed an average of forty percent (40%) any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(d) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings) as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

State Rule Applicability - Individual Facilities

(a) 326 IAC 2-2 (Prevention of Significant Deterioration)
The proposed process tanks are not subject to 326 IAC 2-2, pursuant to USEPA guidance described in a September 9, 1988 letter from Don Clay to David Kee regarding PSD applicability to the WEPCO Port Washington life extension project. The tank replacements qualify as routine repair and replacement under the PSD rules (40 CFR 52.21) and 326 IAC 2-2, and are exempt from the PSD permitting requirements.

(b) 326 IAC 8-5-3 (Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing Operations)
This rule applies to the manufacture of pharmaceutical products by chemical synthesis. This section applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of organic compounds , transfer of organic compounds, extraction equipment , filters, crystallizers, and centrifuges that have the potential to emit 15 pounds per day or more. The sections that are applicable to Lilly are (b)(1), (5) and (6).

Section (b)(1) of this rule requires that the VOC emissions coming from all reactors, distillation operation, crystallizers, centrifuges, and vacuum dryers shall be controlled by condensers or equivalent controls. The approximate control efficiency required by 326 IAC 8-5-3(b)(1) when using acetone, which has the worst volatility is around 90%.

Lilly is in compliance with this section of the rule, controlling the VOC emissions using either condensers in series with the Regenerative Thermal Oxidizer (RTO), or using the RTO alone. Lilly typically uses the existing RTO to control point source VOC emission from the tanks. The RTO, which has been demonstrated to achieve VOC removal efficiency in excess of 97%, will meet and exceed the requirement of the rule. If the RTO cannot be used due to safety issues, an alterative control device may be used. An analysis to demonstrate the alternative controls are equivalent controls will be done before they are used. Lilly would like to continue manufacturing operations in the process vessels included in this application using other existing pollution control equipment that complies with 326 IAC 8-5-3.

Section(b)(5) of this rule requires the owner or operator to install covers on all in process tanks that contain VOC's. Lilly complies with this section by using covers on all in process tanks, these covers are closed unless production sampling, maintenance, or inspection procedures require operator access.

Section (b)(6) of this rule requires the owner or operator to repair all visible leaks containing VOC. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

(c) 326 IAC 8 (Volatile Organic Sources)
There are no other rule in Article 8 that would apply to the proposed process tanks.

(d) 326 IAC 7 (Sulfur Dioxide Emission Limitation)
All facilities with a potential to emit 25 tons per year or 10 tons per hour of sulfur dioxide shall comply with the limitation under this rule.

The sulfur dioxide emissions from the process tanks are not subject to the emissions limitation under this rule, because the limitation are specifically for combustion facilities.

(e) 326 IAC 2-4.1-1 (Toxics Control Rule)
The proposed tanks are not subject to this rule because of the following reasons:

(1) The proposed process tanks are regulated under 40 CFR Part 63, Subpart GGG - National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production, which was promulgated on September 21, 1998. They will be subject to the existing source MACT requirement of that rule.

(2) This project does not constitute construction, reconstruction of a process or production unit because (1) the fabrication, erection or installation covered by this application does not constitute a collection of all the equipment necessary to the production of an intermediate or final product; and (2) the fixed capital cost of this project does not exceed 50% of the fixed capital cost for the replacement of any of the affected process or production unit.

(f) There are no previous permit conditions for the replaced process tanks that will be carried over in this source minor modification, including emissions limit to avoid PSD.

Air Toxic Emissions

Indiana presently requests applicants to provide information on emissions of the 188 hazardous air pollutants (HAPs) set out in the Clean Air Act Amendments of 1990. These pollutants are either carcinogenic or otherwise considered toxic and are commonly used by industries. They are listed as air toxics on the Office of Air Management (OAM) Part 70 Application Form GSD-08.

(a) This source will emit levels of air toxics less than those which constitute a major source according to Section 112 of the 1990 Clean Air Act Amendments.

Since it is difficult to predict the mix of compounds that will be used in Building T-28, Lilly assumed that any one of the following compounds could be emitted (acetonitrile, carbon disulfide, chlorobenzene, dimethylformamide, ethylene dichloride, hexane, hydrochloric acid, methanol, MEK, methyl isobutyl ketone, methyl tert-butyl ether, methylene chloride, toluene, and triethylamine, xylenes and glycol ethers). The potential to emit for combined HAPs are emitted at 32.12 tons per year before control. The existing scrubbers will control the inorganic HAPs, which has a control efficiency of 95%. The controlled inorganic HAPs emissions are at 1.38 tons per year. The existing RTO will control the organic HAPs, which has a control efficiency that meets and exceeds the requirements of 326 IAC 8-5-3. The controlled organic HAPs are at 4.52 tons per year.

Conclusion

The operation of the process tanks Gen'l Tank 28-13, and Gen'l Tank 28-1A shall be subject to the conditions of the attached proposed **Minor Source Modification 157-10818-00006.**